

minute. I would like to say publicly, as I have said to the Senators privately, and to the Presiding Officer, that we have been through a very difficult time while you have been presiding. It really is most helpful, where there is confusion on the floor, to have someone who understands what is going on and who has absolute control of the Senate. You did an outstanding job of presiding. That is not easy.

We have Parliamentarians who help. But it certainly is a tremendous help if you have someone such as the Presiding Officer who makes the decisions on his own. They were all right. I extend my appreciation and our appreciation for the way in which you presided over the Senate during consideration of a most important bill. We have heard enough talk about it.

But this is an important bill. It is an emergency supplemental appropriations bill which will help our troops, help homeland defense, and help veterans.

#### UNANIMOUS CONSENT AGREEMENT—S. 625

Mr. REID. Mr. President, I ask unanimous consent the Senate proceed to the consideration of S. 625, the hate crimes bill, Friday, tomorrow, June 7, at 11 a.m. That is today, I guess.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. REID. For the information of Members, the next vote will be on Monday, at approximately 5:30 p.m. Today there will be no more votes.

#### MORNING BUSINESS

Mr. REID. Mr. President, I ask unanimous consent that the Senate now proceed to a period of morning business with Senators allowed to speak therein for a period not to exceed 5 minutes each.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### VOTE EXPLANATION

Mr. LIEBERMAN. I was not able to vote on the Helms-Frist amendment (Number 3725) to the Supplemental Appropriations bill. I was unavoidably detained. I would like to express my support for this measure and applaud its passage. I co-sponsored the defeated Durbin amendment that would have provided an additional \$500 million towards the global fight against AIDS, malaria, and tuberculosis. I was disappointed that it did not pass tonight. In the absence of the Durbin provisions, I agree with the Senator from Tennessee that we must at least provide the additional \$100 million called for in the Helms-Frist amendment. I ask that the record show that I would have voted in favor of the Helms-Frist Amendment and I support its passage.

#### PERFORMANCE GOALS FOR THE PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2002

Mr. KENNEDY. Mr. President, on May 23, 2002, the Senate passed the Conference Report to H.R. 3448, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Included in Title V of this Conference Report is the reauthorization of the Prescription Drug User Fee Act, "PDUFA".

Performance goals, existing outside of the statute, accompany the reauthorization of PDUFA. These goals represent a realistic projection of what the Food and Drug Administration Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research can accomplish with industry cooperation. The Secretary of Health and Human Services forwarded these goals to the chairmen of the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate, in a document entitled "PDUFA Reauthorization Performance Goals and Procedures." According to Section 502 of the Conference Report, "the fees authorized by amendments made in this subtitle will be dedicated towards expediting the drug development process and the process for the review of human drug application as set forth in the goals in the CONGRESSIONAL RECORD."

Today I am submitting for the RECORD this document, which was forwarded to the Committee on Health, Education, Labor and Pensions on June 4, 2002, as well as the letter from Secretary Thompson that accompanied the transmittal of this document.

I ask unanimous consent it be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

THE SECRETARY OF  
HEALTH AND HUMAN SERVICES,  
Washington, DC, June 4, 2002.

Hon. EDWARD M. KENNEDY,  
Chairman, Committee on Health, Education,  
Labor and Pensions, U.S. Senate Wash-  
ington, DC.

DEAR CHAIRMAN KENNEDY: As you are aware, the Prescription Drug User Fee Act of 1992 (PDUFA), as reauthorized by the Food and Drug Administration Modernization Act of 1997, expires at the end of Fiscal Year 2002. Under PDUFA, the additional revenues generated from fees paid by the pharmaceutical and biological prescription drug industries have been used to expedite the process for the review of prescription drugs, in accordance with performance goals that were developed by the Food and Drug Administration (FDA) in consultation with PDUFA stakeholders.

FDA has worked with various stakeholders, including representatives from consumer, patient, and health provider groups, and the pharmaceutical and biological prescription drug industries, to develop a reauthorization proposal for PDUFA that would build upon and enhance the success of the program. Title 5, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as passed by

the House on May 22, 2002, and by the Senate on May 23, 2002, reflects the fee mechanisms and other improvements developed in these discussions. The performance goals referenced in Section 502 are specified in the enclosure to this letter, entitled "PDUFA Reauthorization Performance Goals and Procedures." I believe they represent a realistic projection of what FDA can accomplish with industry cooperation and both the additional resources identified in the bill and annual FDA appropriations that fully cover the costs of pay and inflation increases for the drug and biologics review process each year.

This letter and the enclosed goals document pertain only to Title 5, Subtitle A (Prescription Drug User Fees) of H.R. 3448, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. OMB has advised that there is no objection to the presentation of these views from the standpoint of the Administration's program. We appreciate the support of you and your staffs, the assistance of other Members of the Committee, and that of the Appropriations Committees, in the reauthorization of this vital program.

Sincerely,

TOMMY S. THOMPSON.

Enclosure.

#### PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES

The performance goals and procedures of the FDA Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), as agreed to under the reauthorization of the prescription drug user fee program in the [cite statute] are summarized as follows:

##### I. REVIEW PERFORMANCE GOALS—FISCAL YEAR 2003 THROUGH 2007

###### A. NDA/BLA submissions and resubmissions

Review and act on 90 percent of standard original NDA and BLA submissions filed during fiscal year within 10 months of receipt.

1. Review and act on 90 percent of priority original NDA and BLA submissions filed during fiscal year within 6 months of receipt.

2. Review and act on 90 percent of Class 1 resubmitted original applications filed during fiscal year within 2 months of receipt.

3. Review and act on 90 percent of Class 2 resubmitted original applications filed during fiscal year within 6 months of receipt.

###### Original Efficacy Supplements

1. Review and act on 90 percent of standard efficacy supplements filed during fiscal year within 10 months of receipt.

2. Review and act on 90 percent of priority efficacy supplements filed during fiscal year within 6 months of receipt.

###### Resubmitted Efficacy Supplements

###### Fiscal Year 2003:

1. Review and act on 90 percent of Class 1 resubmitted efficacy supplements filed during fiscal year 2003 within 6 months of receipt and review and act on 30 percent within 2 months of receipt.

2. Review and act on 90 percent of Class 2 resubmitted efficacy supplements filed during fiscal year 2003 within 6 months of receipt.

###### Fiscal Year 2004:

1. Review and act on 90 percent of Class 1 resubmitted efficacy supplements filed during fiscal year 2004 within 4 months of receipt and review and act on 50 percent within 2 months of receipt.

2. Review and act on 90 percent of Class 2 resubmitted original applications filed during fiscal year 2000 within 6 months of receipt.

###### Fiscal Year 2005:

1. Review and act on 90 percent of Class 1 resubmitted efficacy supplements filed during fiscal year 2005 within 4 months of receipt and review and act on 70 percent within 2 months of receipt.